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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,586

08/08/2005

Masaru Nakatani

4991-0157PUS1

9941

2292 7590 08/17/2010  
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EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

08/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,586	<b>Applicant(s)</b> NAKATANI ET AL.	
	<b>Examiner</b> DIRK BASS	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/12/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response filed June 8, 2010 is acknowledged. Claims 1, 7, 8, and 17-18 are amended. Claims 2, 9, 10, 12, and 13 are cancelled. Claims 1, 3-8, 11, and 14-18 are pending and further considered on the merits.

#### ***Response to Amendment***

In response to the amendment, the examiner modifies the grounds of rejection set forth in the office action dated December 9, 2009.

#### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. **Claims 1, 3-7, 11, and 14-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Inama et al., JP07-136256 (Inama) in view of Nakatani et al., PCT/JP02-00683 as evidenced by Tani et al., US 4576928 (Tani). For purposes of clarity, the examiner is relying on the US publication of PCT/JP02-00683, hereinafter UPISA 2004/0222144 (Nakatani)
3. Regarding claims 1 and 3, Inama discloses an adsorbent capable of whole blood treatment adsorbing low density lipoproteins and fibrinogen (¶ 0003-0004 and Claims 1-2) comprising tryptophan and a polyanionic compound (¶ 0017) immobilized on a water-insoluble porous carrier in order to adsorb fibrinogen (¶ 0015). Inama further discloses an example where the polyanionic compound can be dextran sulfate in order to adsorb low density lipoprotein (¶ 0018). Inama also recognizes optimizing the amount of polyanionic compound and tryptophan to improve the performance of the adsorbent (¶ 0009, 0014), where it would naturally flow to have an amount of the immobilized polyanionic compound in the range of 0.10-1.5  $\mu\text{mol/ml}$  of wet volume of the adsorbent, as evidenced by Tani (col. 7, l. 27-35).
4. Inama does not explicitly disclose the molar ratio of tryptophan to polyanionic compound. However, it has been held that discovery of an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

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5. Inama does not explicitly disclose an adsorbent comprising dextran sulfate. However, Nakatani discloses adsorbents for reducing low density lipoproteins (abstract and examples) comprising dextran sulfate. At the time of invention, it would have been obvious to one having ordinary skill in the art to include dextran sulfate in the adsorbent of Inama in order to efficiently adsorb low density lipoproteins as well as fibrinogen.

6. Moreover, it would have been obvious to one having ordinary skill in the art to include dextran sulfate in the adsorbent of Inama since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

7. Lastly, Inama discloses an example where dextran sulfate is used to adsorb low density lipoprotein (§ 0018). At the time of invention, it would have been obvious to one having ordinary skill in the art to combine dextran sulfate with tryptophan on a porous carrier since it was known that the combination of these elements can be used in blood treatments for adsorbing fibrinogen and low density lipoproteins and the combination would produce no more than predictable results, absent a showing of unexpected results or criticality.

8. Regarding claim 4, Inama in view of Nakatani discloses the water insoluble porous carrier is cellulose (§ 0012).

9. Regarding claims 5 and 14-15, Inama in view of Nakatani discloses the water insoluble porous carrier has a molecular weight exclusion limit of  $5 \times 10^5$  to  $1 \times 10^8$  for globular proteins (§ 0011).

10. Regarding claims 6 and 16, Inama in view of Nakatani discloses a method comprising bringing the adsorbent described above into contact with a body fluid containing low density lipoproteins and fibrinogen (§ 0001).

11. Regarding claims 7 and 17-18, Inama in view of Nakatani discloses an adsorber comprising a container having an inlet, and outlet, and means for preventing an outflow of and adsorbent to the outside (§ 0007), the container being filled with the adsorbent described above.

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12. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Inama in view of Nakatani as relied upon in the rejection above, and in further view of Kuroda et al., US 5286449 (Kuroda) as evidenced by Tani.

13. Regarding claim 8, Inama in view of Nakatani does not appear to disclose the capacity of the adsorber. However, Kuroda discloses the capacity of an adsorber to be 100ml to 400ml (col. 16, l. 25).

14. At the time of invention, it would have been obvious to a routineer in the art to modify the adsorber of Inama in view of Nakatani to include the capacity of the adsorber of Kuroda in order to stably conduct whole blood treatment with a decreased blood volume being taken outside the body (col. 16, l. 25-31).

### ***Response to Arguments***

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

/DRB/  
Dirk R. Bass